Medtronic Graft Delivery Syringe
510(K) Summary – K062986
December 2006

DEC - 8 2006

I. **Company:** **Medtronic USA, Inc.**
1800 Pyramid Place
Memphis, TN 38132

Contact: **Christine Scifert**
Group Director, Regulatory Affairs
(901) 396-3133

II.

Proposed Proprietary Trade Name:	Medtronic Graft Delivery Syringe
Classification Name:	Piston Syringe
Product Code:	FMF
Regulation No.:	880.5860

III. **Product Description/Purpose of Application**

The purpose of this application is to notify the FDA of our intent to market the Medtronic Graft Delivery Syringe as a means to deliver graft material to an orthopedic surgical site.

IV. **Indications**

The Medtronic Graft Delivery Syringe is intended to provide the surgeon with a means to mix autologous blood or bone marrow with allograft, autograft, demineralized bone, or synthetic bone graft materials and to deliver these materials to all orthopaedic surgical sites.

V. **Substantial Equivalence**

Documentation was provided which demonstrated the Medtronic Graft Delivery Syringe to be substantially equivalent to previously cleared graft delivery systems such as Harvest Technologies Corp.'s Harvest Graft Delivery System, (K043261, SE 03/11/05), Depuy's Symphony Graft Delivery System, K003286 (01/18/01), the Imbibe Piston Syringe (K011087, SE 09/19/01), the Imbibe Bone Marrow Aspiration Syringe (K023074, SE 03/11/03) and the Imbibe II Piston Syringe, (K030208, SE 04/16/03).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Sofamor Danek
% Mr. Lee Grant
Supervisor, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

DEC - 8 2006

Re: K062986
Trade/Device Name: Medtronic Graft Delivery Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMF
Dated: November 10, 2006
Received: November 13, 2006

Dear Mr. Grant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

December - 2006

510(k) Number (if known): K062986

Device Name: Medtronic Graft Delivery Syringe

Indications for Use: The Medtronic Graft Delivery Syringe is intended to provide the surgeon with a means to mix autologous blood or bone marrow with allograft, autograft, demineralized bone, or synthetic bone graft materials and to deliver these materials to all orthopaedic surgical sites.

Prescription Use ___X__ **AND/OR** **Over-The-Counter Use _____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062986